

On page 1, line 26, delete “which”.

On page 1, line 27, delete “are equipped with tip protector comprising” and insert “wherein a tip protector comprises”.

On page 1, line 28, delete “actuated” and insert “displaced”. On the same line, delete “to” and insert “into the”.

On page 1, line 29, delete “design predetermines” and insert “such mechanism leads to inevitable”.

On page 1, line 30, add the word “and” before the word “high” and delete “, i.e.” and insert a “..”.

On page 2, delete lines 1 and 2 and on line 3 delete “piercing members are present, that is the tip and the protectors themselves. When” and insert “Moreover, when”.

On page 2, line 5, delete “therefore,” and insert a “.” at the end of the sentence.

On page 2, line 6, change “further” to “Further”.

On page 2, delete lines 12 - 29 in their entirety.

On page 2, line 30 add “a” before “shield”. Also on line 30 delete “known from the” and insert “disclosed by”.

On page 3, line 1, delete “in the patent”.

On page 3, line 6, delete “it” and insert “the latter”.

On page 3, line 10, delete “known from the” and insert “disclosed by”.

Please make the following changes to the Summary of the Invention section of the originally submitted specification:

On page 3, delete lines 15-22 in their entirety.

On page 3, delete lines 25-28 in their entirety.

On page 3, line 29 after “is” insert “the”.

On page 4, delete lines 7-8 in their entirety.

On page 4, delete lines 13-30 in their entirety.

Delete pages 5 through 16 in their entirety.

On page 17, delete lines 1-23 in their entirety and insert the following: "The above noted objectives are accomplished by a safety trocar assembly having a portal unit with elongated obturator removably inserted through the cannula and having a handle on its proximal end and a penetrating end on its distal end. The penetrating end is exposed through the cannula open distal end and has a cutting means, a penetrating apex, and a sloping side wall immovable relative to obturator. The obturator is provided with a protector means having a bias means and a movable penetrating apex shield that in its retracted position opens the penetrating apex and in its extended position closes the penetrating apex preventing it from any contact with patient's organs. In the projection onto transverse plane, the obturator sloping side wall surrounds the penetrating apex shield. It means that the penetrating and, consequently, also the penetrating apex shield have little cross section dimensions in comparison with the obturator. This allows reduction of the resistance of body tissue during penetrating apex shield displacement to its extended position and provides fast acting protection of the penetrating apex immediately after the penetration of penetrating apex distal end into the body cavity, however, before the penetrating end has been fully inserted. Further dilation of the orifice in the body wall is carried out by cutting means located on the sloping side wall. The penetrating apex shield is made tubular of circular or flattened cross section, totally closed or having a slot on one side. The distal edge of this shield forms a fence precluding the introduction, jamming, and engagement of tissue fibers of the body cavity wall between the penetrating apex shield and the penetrating apex as well as between the penetrating apex shield segments. As a result, the injury of body cavity wall is decreased and trocar passing through body cavity wall is facilitated.

The shield for protection of the cutting means is characterized by a local comparative height equal to the ratio of local maximal shield height to a local maximal shield width measured in the same local obturator transverse plane. This parameter characterizes such properties of the protector shield as the resistance of body tissue to shield displacement to its extended (protected) position and velocity of this displacement. The less the value of this parameter the less the tissue resistance and the faster the shield displacement to extended position. According to the present invention, the shield, particularly made plate-shaped, has maximal value of the local comparative height less than 0.5. This shield is a low profile shield and the perimeter of its cross section insignificantly exceeds the perimeter of tissue incision made by the cutting means. Moreover, the height of this plate-shaped shield (the plate thickness) amounts 0.4 to 2 mm for obturator with outer diameter 10 to 12.5 mm and 0.4 to 1.2 mm for obturator with outer diameter 5 to 6.5 mm. This shield is a fast acting protector entering the tissue incision without substantial resistance of tissue incision edges and enabling the shield entry the body cavity immediately after entry there the cutting means. As a result, the risk of patient internal organ injury is significantly decreased.

In version embodiment, a safety trocar assembly comprises a penetrating means with at least two penetrating zones and a protector means with independent protector members, made as shields, for independent protection of each of said penetrating zones, and a resilient bias means for each of the protector members. This protects the penetrating zone (knife) which enters the body cavity independently of another penetrating zones (knives) which have not yet entered the body cavity and continue to cut the tissue. In version embodiment, there are distal and proximal penetrating zones provided with a distal and a proximal independent shield, respectively. The distal penetrating zone is the first one that enters the body cavity and is a main cause of internal organ injury, so its independent and fast protection eliminates trocar procedure complications.

In version embodiment, the displacement of the proximal shield from the extended position to the retracted position demands greater force than identical displacement of the distal shield. That can be achieved by larger rigidity of the bias means (in the form of a spring) of the proximal shield than one of the distal shield. As a result, the proximal penetrating zone forms such final dimensions of orifice that is accurately adapted to the cannula outer diameter. Described penetrating and protector means have so simple a design (for example, making protector and biasing members as a one detail) so as to permit their arrangement in the limits of obturator distal part. Such implementation increases trocar reliability and reduces its manufacturing cost."

Please make the following changes to the Brief Description of the Drawings of the originally submitted specification:

On page 18, delete lines 16-19 in their entirety.

On page 18, line 20, change "19" to "15".

On page 18, line 21, change "20" to "16" and "19" to "15".

On page 18, line 22, change "21" to "17" and "19" to "15".

On page 18, line 23, change "22" to "18" and "21" to "17".

On page 18, line 24, change "23" to "19" and "22" to "18".

On page 18, line 25, change "24-29" to "20-25".

On page 18, line 27, change "30" to "26".

On page 18, line 28, change "31" to "27" and "30" to "26".

On page 18, line 29, change "32" to "28" and "30" to "26".

On page 18, line 30, change "33" to "29" and "30" to "26".

On page 19, line 1, change "34" to "30" and "33" to "29".

On page 19, line 2, change "35" to "31" and "33" to "29".

On page 19, delete lines 4-8 in their entirety.

On page 19, line 9, change "41" to "32".

On page 19, line 10, change "42" to "33" and "41" to "32".

On page 19, line 11, change "43" to "34" and "41" to "32".

On page 19, line 12, change "44" to "35" and "41" to "32".

On page 19, line 13, change "45" to "36" and "41" to "32".

On page 19, line 14, change "46" to "37" and "41" to "32".

On page 19, line 15, change "47" to "38" and "41" to "32".

On page 19, line 16, change "48" to "39" and "41" to "32".

On page 19, line 18, change "49" to "40" and "41" to "32".

On page 19, line 20, change "50" to "41" and "41" to "32".

On page 19, line 22, change "51" to "42".

On page 19, line 24, change "52" to "43" and "51" to "42".

On page 19, line 25, change "53" to "44" and "51" to "42".

On page 19, line 26, change "54" to "45" and "51" to "42".

On page 19, line 27, change "55" to "46" and "51" to "42".

On page 19, line 29, change "56" to "47" and "55" to "46".

On page 19, line 30, change "57" to "48" and "51" to "42".

On page 20, line 1, change "58" to "49" and "57" to "48".

On page 20, line 2, change "59" to "50".

On page 20, line 3, change "60, 61" to "51, 52" and "59" to "50".

On page 20, line 5, change "62" to "53" and "59" to "50".

On page 20, line 6, change "63" to "54" and "59" to "50".

On page 20, line 8, change "64-72" to "55-63".

On page 20, delete lines 10-14 and lines 25-30 in their entirety.

On page 20, line 15, change "77" to "64".

On page 20, line 17, change "78" to "65" and "77" to "64".

On page 20, line 18, change "79" to "66" and "77" to "64".

On page 20, line 19, change "80" to "67" and "79" to "66".

On page 20, line 20, change "81" to "68" and "79" to "66".

On page 20, line 22, change "82" to "69".

On page 20, line 23, change "83-85" to "70-72" and "82" to "69".

On page 21, delete lines 1-4 in their entirety.

Please make the following changes to the Detailed Description of Preferred Embodiments section of the originally submitted specification:

On page 22, line, 15, delete "Preferably, the distal portion extends".

On page 22, delete lines 16-19.

On page 25, delete lines 24-30.

Delete page 26.

On page 27, line 1, delete "19-29" and insert "15-25".

On page 27, line 3, delete "of the type illustrated in Figures 15-18".

On page 27, line 8, change "27" to "23".

On page 27, line 9, change "29" to "25".

On page 27, line 11, change "19" to "15".

On page 27, line 14, change "20" to "16".

On page 27, line 15, change "21" to "17".

On page 27, line 26, change "22" to "18".

On page 27, line 27, change "23" to "19".

On page 27, line 28, change "22, 23" to "18, 19".

On page 28, line 3, change "22, 23" to "18, 19".

On page 28, line 11, change "24-29" to "20-25".

On page 28, line 13, change "24" to "20".

On page 28, line 16, change "25" to "21".

On page 28, line 18, change "26" to "22".

On page 28, line 20, change "27" to "23".

On page 28, line 23, change "28" to "24".

On page 28, line 24, change "29" to "25".

On page 28, line 27, change "30-35" to "26-31".

On page 29, line 4, change "30" to "26".

On page 29, line 6, change "31" to "27".

On page 29, line 8, change "32" to "28".

On page 29, line 9, change "33" to "29".

On page 29, line 10, change "34" to "30".

On page 29, line 17, change "35" to "31".

On page 29, delete lines 20-30.

On page 30, delete lines 1-9.

On page 30, line 10, change "41-50" to "32-41" and delete "which supplements the embodiment of Figures 36-".

On page 30, line 11, delete "40".

On page 30, line 14, change "41" to "32".

On page 30, line 16, change "43" to "34".

On page 30, line 19, change "44" to "35".

On page 30, line 20, change "45" to "36".

On page 30, line 21, change "46" to "37".

On page 30, line 22, change "47" to "38".

On page 30, line 27, change "47" to "38".

On page 31, line 5, change "48, 49, 50" to "39, 40, 41".

On page 31, line 7, change "48" to "39".

On page 31, line 17, change "50" to "41".

On page 31, line 20, change "51-58" to "42-49" and change "41-50" to "32-41".

On page 31, line 21, change "51" to "42".

On page 31, line 25, change "52" to "43".

On page 31, line 26, change "53" to "44".

On page 31, line 30, change "56" to "47".

On page 32, line 1, change "54-58" to "45-59".

On page 32, line 2, change "54" to "45".

On page 32, line 3, change "55, 56" to "46, 47".

On page 32, line 4, change "57" to "48".

On page 32, line 5, change "58" to "49".

On page 32, line 7, change "54-58" to "45-49".

On page 32, line 15, change "59-72" to "50-63".

On page 32, line 16, change "30-35" to "26-31".

On page 32, line 19, change "70 and 71" to "61 and 62".

On page 32, line 20, change "59" to "50".

On page 32, line 25, change "62" to "53".

On page 33, line 3, change "60, 61, 62" to "51, 52, 53".

On page 33, line 12, change "64-72" to "55-63".

On page 33, line 14, change "64" to "55".

On page 33, line 15, change "65" to "56".

On page 33, line 17, change "66" to "57".

On page 33, line 19, change "67" to "58".

On page 33, line 20, change "68" to "59".

On page 33, line 21, change "69" to "60".

On page 33, line 23, change "70" to "61".

On page 33, line 27, change "71" to "62".

On page 33, line 28, change "72" to "63".

On page 33, delete line 30.

On page 34, delete lines 1-11.

On page 34, line 12, change "77-81" to "64-68" and change "59-72" to "50-53".

On page 34, line 15, change "77" to "64".

On page 34, line 20, change "78" to "65, 67"

On page 34, line 28, change "77, 78" to "64, 65".

On page 35, line 15, change "82-85" to "69-72" and "41-50" to "32-41".

On page 36, line 4, change "83, 84, 85" to "70, 71, 72".

On page 36, line 6, change "83" to "70".

On page 36, line 11, change "83" to "70".

On page 36, line 12, change "84" to "71".

On page 36, delete lines 21-30.

Delete page 37.

Page 38, delete line 1-3.

#### IN THE DRAWINGS

Please cancel all 25 original sheets of drawings, comprising FIGS. 1-94. Insert the enclosed 18 sheets of drawings, comprising FIGS. 1-72.

#### IN THE CLAIMS

Cancel original claims 1-95. Add claims 96-131 as follows:

96. A safety trocar assembly device having:

- a longitudinal central axis;
- a portal unit with elongated, tubular cannula having an open distal end;
- a trocar unit having an elongated obturator adapted to be removably inserted through said cannula,<sup>9</sup> having a handle on a proximal end, and a penetrating end on a distal end, said penetrating end exposed through said distal end of said cannula and having a cutting means for making an orifice in body cavity wall, a penetrating apex, and a sloping side wall<sup>10</sup> that are immovable relative to said obturator;

- a protector means situated on said obturator and having a penetrating apex shield<sup>11</sup> adapted to actuate between a retracted position in which said penetrating apex is open and an extended position in which said penetrating apex is closed by said penetrating apex shield and in the projection onto the plane normal to said longitudinal axis said sloping side wall<sup>12</sup> surrounds said penetrating apex shield;

- said penetrating apex shield surrounds said penetrating apex<sup>13</sup> and has distal edge forming a fence precluding the introduction, jamming, and engagement of tissue fibers of body cavity wall between said penetrating apex shield and said penetrating apex, as well as between said penetrating apex shield segments;<sup>14</sup>

<sup>15</sup> <sup>P24</sup> <sup>16</sup>  
- bias means for biasing said penetrating apex shield toward said extended position and for permitting said penetrating apex shield move to said retracted position in response to a proximally directed force applied to said penetrating apex shield distal edge; said bias means returning said penetrating apex shield to said extended position when the force applied to said penetrating apex shield distal edge is removed, that occurs when said penetrating apex and said penetrating apex shield distal edge have entered a patient's body cavity, however, before said penetrating end has been fully inserted into body cavity.

97. Device according to claim 96, wherein said bias means is made as a spring mounted between said penetrating apex shield and parts of said obturator.

98. Device according to claim 97, wherein said spring is situated in said obturator distal part.

99. Device according to claim 96, wherein said penetrating apex shield is tubular.

100. Device according to claim 96, wherein:

- the displacement vector of said protector between its said extended and retracted positions is in the plane parallel to said longitudinal central axis;

- said cutting means comprises at least one cutting edge having distal end and situated in the plane parallel to said longitudinal central axis so that this plane is the cutting plane of said cutting edge;

- said protector means has a shield for protection of said cutting edge;
- said shield has proximal protected position that is the extreme proximal position of said shield wherein said cutting edge distal end is protected;
- said shield has a screen area and as such serves portion of said outer surface which, when said shield is in said proximal protected position, is located outside said tubular cannula and outside said sloping side wall presenting an open part of said shield in said proximal protected position;
- said shield has a shield height and as such serves the distance from said shield outer surface to said cutting plane;
- said shield has a shield width and as such serves the distance from said shield outer surface to said longitudinal central axis;
- said shield is characterized by a local comparative height equal to the ratio of local maximal said shield height to local maximal said shield width measured in their common local plane perpendicular to said device longitudinal axis;
- said shield is low-profile having maximal said local comparative height that within the limits of said screen area is less than 0.5.

101. Device according to claim 96, wherein said cutting means comprises a penetrating apex cutting means protected by said penetrating apex shield.

102. Device according to claim 100, wherein said penetrating apex is plate-shaped and said penetrating apex shield made as said low profile shield.

103. Device according to claim 100, wherein said cutting means has an outer cutting means having at least one outer cutting member made as a knife situated outside of said penetrating apex shield within the limits of said sloping side wall.

104. Device according to claim 103, wherein there is at least one outer shield for protecting said outer cutting means, therewith said penetrating apex shield and outer shield are movable independently of one another.

105. Device according to claims 102, 103, 104, wherein said penetrating apex cutting means and outer cutting means are made integral on the plate-shaped base, said outer shield is made as low profile shield, and said penetrating apex shield and said outer shield have longitudinal slot, said plate base passes through.

106. Device according to claim 104, wherein said outer shield is tubular and surrounds said penetrating apex, penetrating apex shield, and outer cutting means in said outer shield extended position.

107. Device according to claim 96, wherein said portal unit has:

- a portal housing located on the proximal end of said tubular cannula;
- seals located in said portal housing for prevention a gas leakage from the body cavity;

- a locking means for locking said protector means in said extended position.

108. A safety trocar assembly comprising:

- a trocar unit having elongated obturator with penetrating distal end;
- a longitudinal central axis of trocar assembly;
- a penetrating means for orifice formation in body cavity wall having at least two penetrating zones;
  - a protector means, having independent protector members for independent protection of each of said penetrating zones adapted to independent moving between a retracted and an extended position and a resilient bias means for each of said protector members.

109. Device according to claim 108, wherein there are:

- a portal unit with elongated, tubular cannula having an open distal end;
- a sloping side wall of said penetrating end and as such serves a portion of said penetrating end immovable relative to said tubular cannula during piercing the body tissue;
- said protector members are made as shields for protection of the cutting edges of said penetrating means; each of said cutting edge is situated in a cutting plane parallel to said longitudinal central axis;
- each of said shields has a proximal protected position that is the extreme proximal position of said shields wherein said cutting edges distal end is protected;
- said shield has a screen area and as such serves portion of said shield outer surface which, when said shield is in said proximal protected position, is located outside said tubular cannula and outside said sloping side wall presenting an open part of said shield in said proximal protected position;
- said shield has a shield height and as such serves the distance from said shield outer surface to said cutting plane;
- said shield has a shield width and as such serves the distance from said shield outer surface to said longitudinal central axis;
- said shield is characterized by a local comparative height equal to the ratio of local

maximal said shield height to local maximal said shield width measured in their common local plane perpendicular to said device longitudinal axis;

- at least one said protector member has maximal said local comparative height that within the limits of said screen is less than 0.5.

110. Device according to claim 108, wherein said penetrating means has at least one distal and one proximal said penetrating zones provided with a distal and proximal said protector members, respectively.

111. Device according to claim 110, wherein the displacement of said proximal protector member from said extended position to said retracted position demands greater efforts than identical displacement of said distal protector member.

112. Device according to claim 111, wherein the rigidity of said bias means of said proximal protector member is more than the rigidity of said bias means of said distal protector member.

113. Device according to claim 108, wherein said penetrating zones are situated around said longitudinal axis at regular intervals from each other.

114. Device according to claim 109, wherein said protector members are made as a floating common shield for at least two penetrating zones having said maximal local comparative height that within the limits of said screen area is less than 0.5, said penetrating means made as said cutting members with common cutting edge so that each of said cutting members is protected by its regions of said common shield and each of said common shield regions is biased by its own said bias means thereby converting said regions of common shield into said independent protector members.

115. Device according to claim 114, wherein said common shield and said bias means are made as one detail.

116. Device according to claim 108, wherein said protector members are made as separate shields.

117. Device according to claim 109-116, wherein there are two said cutting members and said protector members are made as plate-shaped said shield plates situated parallel to the said cutting planes of respective said cutting members.

118. Device according to claims 108-116, wherein said shields are tubular, therewith said distal shield of said distal penetrating zone has less diameter than said proximal shield of said proximal penetrating zone and both said shields are arranged equidistantly to one another and to said longitudinal central axis.

119. Device according to claim 108, wherein there is a portal unit with an elongated tubular cannula having an open distal end through which said penetrating end of said obturator is exposed.

120. Safety trocar assembly device having:

- a portal unit with elongated, tubular cannula having an open distal end;
- a trocar unit having an elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said open distal end of said cannula;
- a longitudinal central axis of trocar assembly;
- a penetrating means situated on said penetrating end of said obturator and having at least one penetrating zone with a cutting means that cuts the tissue in the cutting plane parallel to said longitudinal central axis, comprises at least one cutting edge having distal end and situated in said cutting plane;
- a displacement vector of said shield between its said extended and retracted position disposed in the plane parallel to said longitudinal axis of trocar assembly; 112
  - said shield has proximal protected position, as such serves the extreme proximal position of said shield wherein said distal end of said cutting edge is protected;
  - said shield has screen area and as such serves that portion of said shield outer surface which, in said shield proximal protected position, is located outside said tubular cannula and protrudes beyond the bounds of members of said trocar assembly immovable relative to said tubular cannula during piercing the body tissue;
  - said shield has a shield height and as such serves the distance from said shield outer surface to said cutting plane;
  - said shield has a shield width and as such serves the distance from said shield outer surface to said longitudinal central axis;
  - said shield is characterized by a local comparative height equal to the ratio of local maximal said shield height to local maximal said shield width measured in their common local plane perpendicular to said device longitudinal axis;
  - said shield is low-profile shield having maximal said local comparative height that within the limits of said screen area is less than 0.5, therefore said shield is low profile shield and perimeter of the cross section of said shield insignificantly exceeds the perimeter of the tissue incision made by said cutting means thereby enabling said shield entry said incision without substantial resistance of the edges of said incision.

121. Device according to claim 120, wherein inner diameter of said tubular cannula is within 10 mm to 12.5 mm range and said maximal height of said shield along the entire said screen area is less than 3 mm, preferably 0.4 to 2 mm.

122. Device according to claim 120, wherein inner diameter of said tubular cannula is